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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---------------------------|----------------------------------|----------------------|-------------------------|------------------|--|
| 10/687,262 | 10/16/2003 | Klaus Rudolf | 1/1402 | 9943 | |
| 28501 | 7590 02/21/2006 | | EXAMINER | | |
| | P. MORRIS ER INGELHEIM CORPOR | PERLINGER, SARAH E | | | |
| | ER INGELHEIM CORFOR BURY ROAD | ART UNIT | PAPER NUMBER | | |
| P. O. BOX 3 | 68 | 1625 | | | |
| RIDGEFIELD, CT 06877-0368 | | | DATE MAILED: 02/21/2006 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Ар | plication No. | 7 | Applicant(s) | | | | |
|---|--|--|--|---|--|--------------|--|--|--|
| Office Action Summary | | 10 | /687,262 | ı | RUDOLF ET AL. | | | | |
| | | Ex | aminer | 7 | Art Unit | | | | |
| | | Sa | rah E. Perlinger | | 1625 | | | | |
| Period fo | The MAILING DATE of this communic r Reply | ation appears | on the cover sheet w | vith the co | rrespondence ad | dress | | | |
| WHIC - Exter after - If NO - Failui Any r | CRTENED STATUTORY PERIOD FOR HEVER IS LONGER, FROM THE MAN SISIONS of time may be available under the provisions of SIX (6) MONTHS from the mailing date of this community period for reply is specified above, the maximum stature to reply within the set or extended period for reply withi | ILING DATE 37 CFR 1.136(a). lication. tory period will app II, by statute, cause | OF THIS COMMUNI In no event, however, may a oly and will expire SIX (6) MO the the application to become A | ICATION. reply be timely NTHS from the ABANDONED | y filed e mailing date of this co (35 U.S.C. § 133). | | | | |
| Status | | | | | | | | | |
| 1)🖂 | Responsive to communication(s) filed | on 16 Octob | er 2003. | | | | | | |
| , | This action is FINAL . 2b)⊠ This action is non-final. | | | | | | | | |
| , | ,— | | | | | | | | |
| , | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | | |
| Dispositi | on of Claims | | | | | | | | |
| 4)⊠ Claim(s) <i>1-11,15 and 16</i> is/are pending in the application. | | | | | | | | | |
| | 4a) Of the above claim(s) <u>12-14</u> is/are withdrawn from consideration. | | | | | | | | |
| 5) | 5) Claim(s) is/are allowed. | | | | | | | | |
| 6)[| ☐ Claim(s) is/are rejected. | | | | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | | | | |
| 8)🖂 | Claim(s) <u>1-11,15 and 16</u> are subject to | restriction a | nd/or election require | ement. | | | | | |
| Applicati | on Papers | | | | | | | | |
| 9) 🗌 🤄 | The specification is objected to by the | Examiner. | | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | | |
| | Replacement drawing sheet(s) including the | ne correction is | required if the drawing | g(s) is obje | cted to. See 37 CF | FR 1.121(d). | | | |
| 11) 🔲 | The oath or declaration is objected to t | by the Exami | ner. Note the attache | ed Office A | ction or form PT | O-152. | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | | | | |
| a)[| Acknowledgment is made of a claim for All b) Some * c) None of: 1. Certified copies of the priority do 2. Certified copies of the priority do 3. Copies of the certified copies of application from the International see the attached detailed Office action | ocuments had ocuments had the priority d al Bureau (PC | ve been received. ve been received in a locuments have been CT Rule 17.2(a)). | Application | n No I in this National | Stage | | | |
| 2) Notic 3) Inform | t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTonation Disclosure Statement(s) (PTO-1449 or Pir No(s)/Mail Date | | | o(s)/Mail Date Informal Pat | | D-152) | | | |

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DETAILED ACTION

1. Claims 1-16 are pending.

2. Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, 15-16 drawn to a piperidine compound wherein R² and R³ do **not** form a ring together, their physiologically acceptable salts, a process for preparing a pharmaceutical composition containing said compound, and a process for preparing the piperidine compound, classified in various classes and subclasses depending on a species election. If this group is elected, an election of species with regard to R¹, R², and R³ will also be required. Further restriction may be required.
- II. Claims 1-11, 15-16 drawn to a piperidine compound wherein R² and R³ form a ring together, their physiologically acceptable salts, a process for preparing a pharmaceutical composition containing said compound, and a process for preparing the piperidine compound, classified in various classes and subclasses depending on a species election. If this group is elected, an election of species with regard to R²-R³ ring size, Y¹, R⁴ and R⁵ will also be required. Further restriction may be required.

The inventions are distinct, each from the other because of the following reasons:

The compounds of groups I-II differ in elements, bonding arrangements and chemical structure to such an extent that a reference anticipating any one group would not render another group obvious, thus unpatentability of any group would not necessarily imply unpatentability of another group. The search for each diverse core structure as delineated is not coextensive with each other and will constitute an enormous burden.

Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent and distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Should applicant traverse on the ground that the groups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Claims 12-14 are drawn to non-statutory "use" claims and have been withdrawn from consideration. In the event that claims 12-14 are amended to read as method claims, rejoinder may be possible.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Sarah E. Perlinger, whose telephone number is (571) 272-5574. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang, can be reached at (571) 272-0562. The fax number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DD 02/14/2006

Celia Chang Primary Examiner Art Unit 1625